R E M A R K S

The present application is in condition for allowance. Early and favorable action by the Examiner is respectfully solicited.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

The rejection of claims 83-98 under 35 U.S.C. §112, first paragraph, as not having adequate written description is respectfully traversed and should be withdrawn.

The rejection of claims 83-98 under 35 U.S.C. §112, first paragraph, as not being enabled is respectfully traversed and should be withdrawn.

The rejection of claims 83-93 under 35 U.S.C. §112, second paragraph, as being indefinite is respectfully traversed and should be withdrawn.

With respect to the rejection of claims 83-98 under 35 U.S.C. §112, first paragraph, as not having adequate written description, it is not clear whether rejection is based on (i) the Office not finding the cited phrases expressly recited in the specification, claims and/or drawings as originally filed or (ii) the Office not being able to recognize the support for the phrases in the extensive list of locations provided in the previous response (see page 2, last three lines through page 3, line 2 of the Office Action). Both possibilities are addressed by the arguments presented below.

The specification, claims and/or drawings as originally filed would reasonably convey to a person of ordinary skill in the relevant art that the Applicant, at the time the application was filed, had possession of the presently claimed invention. There is no requirement that the words in the claims must match those used in the specification disclosure (MPEP §2173.05(e)). Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision (MPEP §2173.05(e)). Newly added claim limitations may be supported in the originally filed disclosure through express, implicit, or inherent disclosure (MPEP §2163(B)). By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it (MPEP §2163.07(a)).

A person of ordinary skill in the art relevant to the presently claimed invention would recognize the claims, when read in light of the specification, as containing subject matter which was described in the specification in such a way as to reasonably convey that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, support for the phrase "selecting one or more disease-influencing genes needed to be processed for medical research" can be found, for example, on

page 11, lines 8-19 of the specification. In particular, the specification recites:

> Accordingly, it is a primary object of the present invention to provide a system and method for creating a database of information about individuals' environments over a period of time. Another object of the present invention is to provide a database containing information about individuals' environments which can be used with existing genomics databases. **A further object of the present invention is to provide a method of using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes** or substances. **It is another object of the present invention to use the disease-influencing genes** or substances **to find drug candidates or drug targets** (page 11, lines 8-19 of the specification, emphasis added by Applicant's representative).

A person of ordinary skill in the relevant art would recognize the phrases "find disease-influencing genes" and "use the disease-influencing genes ... to find drug candidates or drug targets" as supporting the phrase "selecting one or more disease-influencing genes needed to be processed for medical research" as recited in claims 83 and 90. For example, finding drug candidates or drug targets clearly would be recognized as medical research. Using disease-influencing genes found using environmental information about an individual in conjunction with the individual's genotype in the medical research of finding drug candidates or drug targets clearly could reasonably be described as "selecting one or more disease-influencing genes needed to be processed for medical research." As such, written support for the phrase "selecting one

or more disease-influencing genes needed to be processed for medical research" as recited in claims 83 and 90 is implicitly and/or inherently present in the specification as originally filed.

Furthermore, a person of ordinary skill in the relevant art would also recognize the phrase "using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes" as supporting the phrase "to identify one or more individuals having a disease-influencing gene" as recited in claims 90 and 94. It is inherent that if disease-influencing genes are found using individual's genotype information, the individuals having the disease-influencing genes have been identified. Further support for the phrase "to identify one or more individuals having a disease-influencing gene" as recited in claims 90 and 94 can be found on page 31, line 27 through page 32, line 2 of the specification as originally filed). As such, the specification as originally filed would reasonably convey to a person of ordinary skill in the relevant art that the Applicant, at the time the application was filed, had possession of the presently claimed invention and the rejection should be withdrawn.

Similarly, a person of ordinary skill in the art relevant to the presently claimed invention would recognize the phrase "that represents a subset of said genotype information associated with each of said groups" recited in claim 83, when read in light of the specification, as containing subject matter which was described in the specification in such a way as to reasonably convey that the

inventor, at the time the application was filed, had possession of the claimed invention. Specifically, a person of ordinary skill in the relevant art would recognize the differences (e.g., gene difference in FIGS. 15 and 17, gene sequence A and gene sequence B in FIGS. 16, 18 and 20, etc) found when comparing the genotype information of individuals between groups would reasonably be described as a subset of the total genotype information associated with the groups. Another example provided in the specification as originally filed is the use of data mining techniques to find differences in gene sequences (see page 31, lines 1-10 of the specification). It is inherent that a report of the results of the data mining (e.g., individual gene sequences A and B in the example) would be generated or else the data mining would not be useful or advantageous. Furthermore, in connection with FIGS. 2 and 10, the specification states that specific techniques for writing a report generator program to display data are well known in the software art (e.g., see page 24, lines 12-21 of the specification as originally filed). As such, the specification as originally filed would reasonably convey to a person of ordinary skill in the relevant art that the Applicant, at the time the application was filed, had possession of the presently claimed invention and the rejection should be withdrawn.

For the reasons presented above, the phrases "selecting one or more disease-influencing genes needed to be processed for medical research," as recited in claims 83 and 90, "that represents a subset of said genotype information associated with each of said

groups," as recited in claim 83, and "to identify one or more individuals having a disease-influencing gene," as recited in claims 90 and 94, have written support in the specification, claims and/or drawings as originally filed and, therefore, do not constitute new matter. As such, the rejection under 35 U.S.C. §112, first paragraph with respect to the "written description" requirement does not appear to be sustainable and should be withdrawn.

With respect to he rejection of claims 83-98 under 35 U.S.C. §112, first paragraph, as not being enabled, the subject matter of the presently pending claims was described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most connected, to make and/or use the claimed invention. Specifically, FIGS. 1, 2 and 13-20 along with the respective descriptive text does describe the subject matter of the presently pending claims in such a way as to enable one skilled in the art to which it pertains or with which it is most connected, to make and/or use the claimed invention. In particular, the specification provides numerous examples of genotype information and sources (e.g., companies) from which genotype information can be received or obtained (see page 4, line 14 through page 9, line 25 of the specification). The specification further provides examples of comparing genotype information based on groups of individuals formed based upon responses to scripted queries (see FIGS. 16, 18 and 20 as originally filed). As such, the rejection under 35 U.S.C. §112,

first paragraph with respect to the "enablement" requirement does not appear to be sustainable and should be withdrawn.

The Office Action states that Doberstein et. al. (U.S. Pub. No. 2003/0068649; hereinafter Doberstein) was cited regarding paragraphs 0003-0008 to support the position that numerous difficulties are involved in relating gene sequences to other factors even utilizing modern bioinformatics tools. However, Doberstein also states that "The fundamental difficulties associated with working with large collections of nucleic acid sequences, such as genetic libraries, **are alleviated** by linking the expressed peptide with the genetic material which encodes it." (paragraph [0006], lines 1-4 of Doberstein, emphasis added by Applicant's representative). Doberstein then describes commonly used methods of linking proteins to coding nucleic acid molecules (see paragraphs [0006]-[0007] of Doberstein). Doberstein further states that the invention disclosed by Doberstein provides a genetic library which allows easy association of a variant or unknown peptide and its coding sequence and a method of use (see paragraph [0008] of Doberstein).

The statement in the Office Action that "Thus, the clustering of individuals, which has been known for many diseases already has not predictably resulted in gene identification" (see page 5, lines 18-21 of the Office Action) is directly contradicted by the example of Myriad Genetics, Inc. on page 7, lines 12-21 of the specification as originally filed. Furthermore, the Office Action fails to provide any objective evidence to support the

continuation of the previous statement "nor will the practice of the instant invention predictably result in the selection or identification of disease-influencing gene(s) or the identification of individuals having a disease-influencing gene." Rather, the Office appears to be making a determination based upon personal opinion rather than objective evidence of record. The Examiner should **never** make the determination [of enablement] based on personal opinion (MPEP §2164.05, emphasis in original). Furthermore, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect" to comply with 35 U.S.C. 112, first paragraph (MPEP §2164, citation omitted).

A patent need not teach, **and preferably omits**, what is well known in the art (see M.P.E.P. § 2163(II)(A)(2), *In re Buchner,* 929 F.2d 660,661, 18 USPQ2d 133 1, *1332* (Fed. Cir. *1991*); *Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802* F.2d 1367, 1384,231 USPQ 81, 94 (Fed. Cir. 1986) (Emphasis added)). The fact that experimentation may be complex does not necessarily make it undue, **if the art typically engages in such experimentation** (*In re Certain Limited-Charge Cell Culture Microcarriers,* 22 1 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia,* 774 F.2d 1104,227 USPQ 428 (Fed. Cir. 1985)). The specification shows that the art does in fact engage in such experimentation as routine business (see pages 6-8 of the specification). Doberstein et al. provides examples of

various commonly used prior art techniques that use experimentation. Further evidence that sequencing involves routine experimentation is provided by a news release (attached as Exhibit A), dated December 19, 1999, by the National Institutes for Health (NIH) concerning the completion of the decoding of Human chromosome 22 by the Human Genome Project stated that "In deciphering chromosome 22, scientists used the approach that has been developed and widely tested by the Human Genome Project" (see marked section on page 2 of 3 of Exhibit A).

Assuming, *arguendo*, that numerous difficulties are involved in relating gene sequences to other factors even using modern bioinformatics tools (as suggested on pages 6 and 7 of the Office Action and for which Applicant's representative does not necessarily agree), it does not necessarily follow that such difficulties would render a person of ordinary skill in the relevant art incapable of comparing genotype information between groups of individuals, where the groups are formed using responses to scripted queries in the patient profile system, to identify one or more individuals having a disease-influencing gene, as presently claimed. Furthermore, the Office Action fails to present any objective evidence or authority for the conclusion that the difficulties would necessarily lead to unpredictable experimentation or why such experimentation should not be considered routine in the field of genomics. In contrast, the application as originally filed provides numerous examples supporting the predictability of various techniques used in the

relevant art for identifying disease-related gene sequences. Furthermore, the time and difficulty of experiments are not determinative if they are merely routine (MPEP §2164.06). For example, an expense of approxiately $50,000 and a time of 6-12 months standing alone failed to show undue experimentation (MPEP §2164.06(I), citing United States v. Telectronics, Inc., citation omitted). As such, the rejection under 35 U.S.C. §112, first paragraph with respect to the "enablement" requirement does not appear to be sustainable and should be withdrawn.

With respect to the rejection of claims 83-93 under 35 U.S.C. §112, second paragraph, as being indefinite, claims 83 and 90 would apprise one of ordinary skill in the art of their scope and, therefore, serve the notice function required by 35 U.S.C. 112, paragraph 2. The mere fact that the body of a claim recites additional elements which do not appear in the claim's preamble does not render the claim indefinite under 35 U.S.C. 112, second paragraph (MPEP §2173.05(e)). Contrary to the position taken in the Office Action (see page 8, lines 1-6 of the Office Action), the recitation in claim 83 of "generating a report for presentation on a display that represents a subset of said genotype information associated with each of said groups" is not necessarily not related to selecting one or more disease-influencing genes. Specifically, claim 83 further recites "defining a plurality of groups by categorizing the individuals having similar profiles based on the responses; after defining said groups, receiving genotype information for individuals in each of said groups; and comparing

said genotype information between said groups." The specification states that:

> A further object of the present invention is to provide a method of using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes or substances. It is another object of the present invention to use the disease-influencing genes or substances to find drug candidates or drug targets (see page 11, lines 13-19 of the specification).

One of ordinary skill in the art would recognize that comparing said genotype information between said groups and generating a report for presentation on a display that represents a subset of said genotype information associated with each of said groups (e.g., genotype differences between the groups) would be reasonable steps in a method for selecting one or more disease-influencing genes to be processed for medical research (e.g. used to find drug candidates or drug targets, etc.), as presently recited in the preamble of claim 83. Thus, one of ordinary skill in the art reading claim 83 in light of the specification would be reasonably apprised of the scope of the claimed invention. As such, the rejection of claims 83-89 under 35 U.S.C. §112, second paragraph, does not appear to be sustainable and should be withdrawn.

Similarly, with respect to claim 90, one of ordinary skill in the art reading claim 90 in light of the specification would recognize that identifying one or more individuals having a disease-influence gene would be a reasonable step in a method for selecting one or more disease-influencing genes needed to be

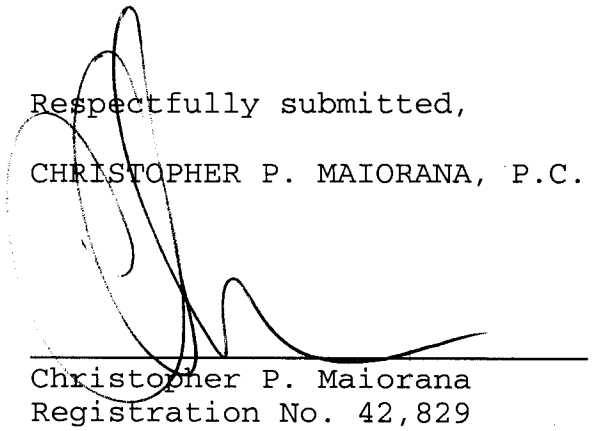
processed for medical research as recited in the preamble of claim 90. For example, the specification provides an example of a company targeting families with a history of genetic disease and collecting their genetic material in order to identify hereditary disease-causing genes by using positional cloning and protein interaction studies in combination with targeted discovery gene sequencing. The specification further points out that the by using these techniques, the company has been able to locate and identify eight disease related gene sequences, which have been used to develop new therapeutics (see page 7, lines 12-21 of the specification). Thus, one of ordinary skill in the art reading claim 90 in light of the specification would be reasonably apprised of the scope of the claimed invention. As such, the rejection of claims 90-93 under 35 U.S.C. §112, second paragraph, does not appear to be sustainable and should be withdrawn.

No art based rejections are presented in the Office Action. As such, the presently claimed invention is believed to be fully patentable and the rejections should be withdrawn.

Accordingly, the present application is in condition for allowance. Early and favorable action by the Examiner is respectfully solicited.

The Examiner is respectfully invited to call the Applicant's representative at between the hours of 9:00 a.m. and 5:00 p.m. ET at 586-498-0670 should it be deemed beneficial to further advance prosecution of the application.

If any additional fees are due, please charge Deposit Account No. 50-0541.



Respectfully submitted,

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c/o Sandeep Jaggi
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Human Chromosome 22: First to be Decoded

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December 1, 1999

Scientists complete first chapter of book of life with decoding of chromosome 22

An international team of researchers has achieved a scientific milestone by unraveling for the first time the genetic code of an entire human chromosome.

Reported in this week's issue of Nature (Dec. 2), researchers at the Sanger Centre near Cambridge, England; University of Oklahoma, Norman, OK; Washington University, St. Louis, MO; and Keio University in Japan have succeeded in deciphering the sequence of the 33.5 million "letters," or chemical components, that make up the DNA of chromosome 22.

This sequence includes the longest, continuous stretch of DNA ever deciphered and assembled. It is over 23 million letters in length.

Each human gene is made up of a series of chemical building blocks represented by letters, A (adenine), T (thymine), G (guanine) and C (cytosine). The number and order of these letters, also called bases, determine what we are, how we look, and the diseases to which we may be predisposed. The chromosome 22 team has deduced the text of one chapter of the human genetic instruction book.

The next mammoth task is to determine what it all means. Sequencing and mapping efforts have already revealed that chromosome 22 is implicated in the workings of the immune system, congenital heart disease, schizophrenia, mental retardation, birth defects, and several cancers including leukemia. But, the scientific team agrees that many more secrets are to be discovered in this decoded text.

The sequencing of chromosome 22 permits scientists for the first time to view the entire DNA of a chromosome.

"This is the first time that we have been able to see the organization of a chromosome at the base pair level," said Dr. Ian Dunham, senior research fellow at the Sanger Centre and leader of the research team that deciphered chromosome 22. "This immediately suggests new experiments and avenues of research which can be pursued."

"To see the entire sequence of a human chromosome for the first time is like seeing an ocean liner emerge out of the fog, when all you've ever seen before were rowboats," said Dr. Francis Collins, director of the National Human Genome Research Institute of the National Institutes of Health which supported the U.S. contribution to the sequencing of chromosome 22.

University of Oklahoma scientist Dr. Bruce Roe, one of the researchers who deciphered the sequence of chromosome 22, added, "It's incredible. For the first time we can stand back and view a picture of all the structures and other features of a human chromosome, to see how a chromosome is organized. Now we can begin to understand where genes are located on chromosomes, how they express themselves, how deletions that give rise to disease-causing mutations occur, and how chromosomes are duplicated and inherited."

Chromosome 22 is the first of 23 human chromosome pairs to be deciphered because of its relatively small size and its association with several diseases and because of the groundwork of several scientists beginning in the early 1990s.

Because protein-coding genes do not seem to occur on the short arm of chromosome 22, the scientists focused on the chromosome's long arm, which is richer in genes relative to other human chromosomes. Ninety seven percent of this arm was sequenced.

The sequence contains 11 gaps or areas that could not be deciphered with current technology. The location and size of the gaps were determined. The 33.5 million bases of sequenced DNA are extremely high quality with an error rate of less than one in 50,000 bases.

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The sequence reveals the following about the landscape of chromosome 22:

- A total number of at least 545 genes and 134 pseudogenes (genes that once functioned but no longer do) were detected on the chromosome, with 200 to 300 additional ones likely. If representative of other chromosomes, this count suggests that the total number of genes on all human chromosomes will not be substantially more or less than the previously estimated number of 80,000.
- The genes range in size from 1,000 to 583,000 bases of DNA with a mean size of 190,000 bases. A total of 39 percent of the chromosome is copied into RNA (exons and introns), while only 3 percent of the chromosome encodes protein.
- A total of 247 genes were revealed by computer analyses to be identical to previously identified human genes or protein sequences. Computer analysis of the chromosome 22 sequence found 150 additional genes with DNA sequence similarity to known genes. An additional 148 predicted genes containing sequence homologous to known genetic markers (ESTs) were identified.
- Several gene families appear to have arisen by tandem duplication. There are families of genes that are interspersed among other genes and distributed over large chromosomal regions.
- There is unexpected long-range complexity of the chromosome with an elaborate array of repeat sequences near the centromere of the chromosome. The existence of so much repetitive DNA information could help explain how this chromosome rearranges or reshuffles its DNA, leading to human disorders such as DiGeorge syndrome, which includes a form of mental retardation, and how chromosome structure changes over time.
- An unexpected finding shows several regions where recombination is increased, and others where it is suppressed, and these will probably play a role in health and disease.

Comparing the chromosome 22 sequence to known gene sequences of the mouse, a lab animal frequently used to facilitate understanding of human genetic disorders, the research team found 160 human genes that have comparable sequences in the mouse. Examining the chromosomal locations of the mouse genes that have counterparts on the human chromosome 22 shows that the order of the genes along the chromosome in the two species is genetically conserved, although the mouse homologs of human genes on chromosome 22 are dispersed to eight different mouse chromosomal regions.

The sequencing of the DNA of chromosome 22 was conducted as part of the international Human Genome Project, which involves scientists in the U.S., England, Japan, France, Germany and China.

In deciphering chromosome 22, scientists used the approach that has been developed and widely tested by the Human Genome Project. This approach involves sequencing overlapping cloned segments of DNA from known locations on the chromosome.

Until now, scientists were uncertain about whether an entire human chromosome could be sequenced in this manner. For example, they did not know whether insurmountable problems would prevent assembling their sequencing data. The presence of a small number of unclonable gaps was not unexpected, but the scientists carrying out this project adhered to the agreed upon standard that a chromosome should not be considered "essentially complete," until the sequence of regions that are clonable and sequenceable with current technology have been determined to high accuracy, and the sizes of any remaining gaps have been determined.

"That chromosome 22 was essentially sequenced by using overlapping clones increases our confidence that the Human Genome Project will be able to complete a 'working draft' of the DNA sequence of the human genome in Spring 2000 and finish it by 2003," said Dr. Richard Wilson, co-director of the Genome Sequencing Center at Washington University School of Medicine in St. Louis and member of the research team that deciphered chromosome 22.

The results of the Human Genome Project, which are freely accessible through public databases such as GenBank (www.ncbi.nlm.nih.gov/genome/seq), give scientists insight into the way genes are arranged along a strip of DNA and paves the way for major advances in the diagnosis and treatment of disease.

Knowing the identity and order of the chemical components of the DNA of the 23 pairs of chromosomes that are found in almost every human cell provides a tool to determine the basis of health and disease. "The fact that all of this information is now freely available for scientists to use, without the constraints of patents and fees, is of major importance, if the knowledge of our genetic make-up is to be used for the good of mankind," said Dr. Michael Morgan, chief executive of the Wellcome Trust Genome Campus, which is home to the Sanger Centre.

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